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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
087441,443	05/15/95	Houghton	M 0063.024

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18M1/1016

EXAMINER
ZEMAN, M

ART UNIT	PAPER NUMBER
1815	4

DATE MAILED: 10/16/96

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 7/24/95

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 10 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 10 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

- SEE OFFICE ACTION ON THE FOLLOWING PAGES -

Serial Number: 08/441,443

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Art Unit: 1815

DETAILED ACTION

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1815.

Double Patenting

2. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

3. Claim 10 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 10 of copending Application No. 08/440,755. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

4. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 recites: "purified HCV". The metes and bounds of this claim are not clear. No details as to the degree and method of purification of the claimed virus are stated. No strain of HCV is recited. Purification of a compound can range from passage of a fluid through a filter, to HPLC purification. The components that make up HCV are not recited such that the limits of the claim are clear. It is not clear how many or which polypeptides (and polynucleotides) of HCV constitute the whole HCV.

5. Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. None of the specifications as filed to date disclose a method of purification of HCV. The method proposed in the disclosure that suggests using an antibody to capture particles from patient sera does not definitively show that complete viral particles are purified. Using HCV specific antibodies in the manner described in the disclosure will also result in the binding of soluble non-virion-associated HCV polypeptides, and potentially the binding of cross-reacting non-HCV-specific polypeptides.

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Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

7. Claim 10 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Prince and under 35 U.S.C. 102(e) as being anticipated by any of Seto, Seto, Coursaget, or Wands.

Claim 10 is drawn to isolated HCV. Prince (Prince et al. 1984 Lancet, Nov 10 p 1071) discloses the use of sera from a patient who developed post-transfusion NANB hepatitis for the infection of chimpanzee hepatocyte cultures. (The Hutchinson inoculum, p1071, Materials and Methods) Also disclosed are other inoculum derived from NANBH infected chimpanzees.

Seto (US Patent 4,673,634) discloses the isolation of the source of Non-A Non-B (NANB) Hepatitis (later named Hepatitis C Virus). Seto (US Patent 4,707,439) also discloses a transmissible NANB hepatitis.

Coursaget (US Patent 4,464,474) discloses the isolation of a NANB viral particle.

Wands (US Patent 4,870,026) discloses the isolation of a NANB viral particle.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marian Knode can be reached on (703) 308-4311.

The fax number for this Art Unit is (703) 305-7939.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

mkz

October 10, 1996


MICHAEL P. WOODWARD
PRIMARY EXAMINER
GROUP 1800